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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,075	04/14/2004	Mary E. Gerritsen	P2014R1	7011
9157 7590 04/10/2007 GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			EXAMINER LI, RUIXIANG	
			ART UNIT 1646	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	
3 MONTHS			04/10/2007	
			DELIVERY MODE PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/824,075

Applicant(s)

GERRITSEN ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04/14/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u>                                    | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/10/2004, 02/22/2005, 01/20/2006.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II, claims 13-20 in the reply filed on 01/18/2007 is acknowledged. Applicant's preliminary amendments filed on 09/27/2004 and 01/18/2007 have entered in full. Claims 1-12 and 21-29 are canceled. Claims 13-20 are pending and under consideration.

### ***Information Disclosure Statement***

2. The information disclosure statements filed on 01/20/2006, 02/22/2005, and 11/10/2004 have been considered by the examiner.

### ***Drawings***

3. The drawings submitted on 04/14/2004 are accepted by the examiner.

### ***Claim Rejections—35 USC §112, 1<sup>st</sup> paragraph***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 13-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Possession may be shown, for example, by describing an actual reduction to practice of the claimed invention. A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose.

It is not the case here. Claims 13-20 are drawn to a method of selectively inhibiting an angiogenic process promoted by a first angiogenic factor but not the angiogenesis process promoted by a second angiogenic factor, comprising administering to a cell exposed to both factors an effective amount of STC-1 or variant thereof, wherein the STC-1 or a variant thereof inhibits at least one step of the angiogenic process promoted by the first angiogenic factor but not the second angiogenic factor. The instant disclosure fails to describe an actual reduction to practice of the claimed invention. There is no showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose.

What's disclosed here is that human STC-1 inhibits migration of human umbilical vein endothelial cells (HUVECs) induced by HGF (Fig. 2, page 55 of

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the specification) and reduces endothelial cord formation on Matrigel induced by 20 ng/ml HGF (Fig. 4, page 56 of the specification), but has no effect on migration of HUVECs induced by bFGF or VEGF and on proliferation of HUVECs stimulated by HGF (10 ng/ml), bFGF (10 ng/ml), and VEGF (10 ng/ml) (page 55 of the specification). However, there is no disclosure of any other angiogenic factors or any other type of cells; there is no evidence showing that human STC-1 has no effect on bFGF or VEGF-induced angiogenesis. More importantly, there is no showing that STC-1 inhibits any step of the angiogenic process of a cell promoted by HGF but not bFGF or VEGF when the cell was exposed to both HGF and bFGF (or VEGF), needless to say any other angiogenic factors. Thus, the specification fails to provide adequate written description for the instantly claimed invention.

Moreover, the claims recite "STC-1 or a variant thereof". The term "STC-1 polypeptide" refers in the specification (page 8) to a polypeptide comprising the amino acid sequence listed in Figure 6 (SEQ ID NO: 2) and STC-1 polypeptide variants, which refers to a polypeptide having at least one of the biological activities of the STC-1 polypeptides and having at least about 80% amino acid sequence identity with SEQ ID NO: 2 (page 8 of the specification).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties,

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functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

The claims do not require that the STC-1 variant possess any particular conserved structure nor disclosed distinguishing feature. The instant disclosure of a human STC-1 polypeptide set forth in SEQ ID NO: 2 does not adequately support the scope of the recited genus, which encompasses a substantial variety of homologues or variants of the STC-1 polypeptide of SEQ ID NO: 2. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant disclosure fails to provide sufficient description information, such as definitive structural or functional features of the recited genus of STC-1 variants. There is no description of the conserved regions that are critical to the structure and function of the genus recited. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. The prior art teaches the human STC-1 polypeptide of SEQ ID NO: 2 (see, e.g., US 2002/0042372 A1, April 11, 2002). However, the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed STC-1 variants.

Accordingly, one skilled in the art would not recognize from the

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disclosure that the Applicants were in possession of the claimed methods at the time the application was filed.

***Claim Rejections—35 USC§ 112, 2<sup>nd</sup> paragraph***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 13-20 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-20 are indefinite because they recite “STC-1”. Such a term is determined arbitrarily and may change with time. For clarity, it is suggested that the term be spelled out in each independent claim and modified with a SEQ ID NO.

***Claim Objections—Minor Informalities***

8. Claims 13, 19, and 20 are objected to because of the following informalities:

(i). claim 13 is objected to because the word “and” in line 2 between “a first angiogenic factor” and “but not” is not needed; (ii). Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 13 recites wherein the STC-1 or a variant thereof inhibits at least one step of the



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angiogenic process promoted by the first angiogenic factor but not the second angiogenic factor”, whereas claim 20 recites “ wherein STC or variant thereof does not *substantially inhibit* ...”. Thus, claim 20 does not further limit the scope of the invention claimed in claim 13. Claim 19 is objected for the same reason.

Appropriate correction is required.

### ***Conclusion***

9. No claims are allowed.

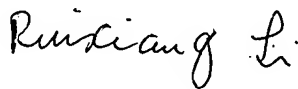
### ***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see

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<http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.



Ruixiang Li, Ph.D.  
Primary Examiner  
March 29, 2007

RUIXIANG LI, PH.D.  
PRIMARY EXAMINER